

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
UTILITY PATENT APPLICATION

*POLYMER COMPOSITES FOR BIOMEDICAL APPLICATIONS AND  
METHODS OF MAKING*

**CROSS-REFERENCE TO RELATED APPLICATION**

This application is a Continuation-In-Part of U.S. Patent Application Serial No. 10/456,149 filed June 5, 2003, titled "Microspheres with Sacrificial Coatings for Vaso-Occlusive Systems", which is incorporated herein by this reference. This application is related to U.S. Patent Application Ser. No. 10/779,075 filed February 14, 2004 titled "Polymer Composites and Methods of Making", which is incorporated herein by this reference.

**FIELD OF THE INVENTION**

This invention relates to a biomedical polymer composite that exhibits ultra-low thermal conductivity properties as well as optional electrical resistivity. In one embodiment, the polymer composite is formed into an embolic filament for occluding an arteriovascular malformation (AVM) wherein electrical energy can be used to sacrifice, melt and divide any suitable length of the filament for filling the AVM without any collateral thermal effects within the vessel lumen.

**BACKGROUND OF THE INVENTION**

Various devices and techniques have been developed for occluding aneurysms or other vascular deformations. A common type of aneurysm treatment utilizes a detachable coil that is fed into the aneurysm to substantially occupy the aneurysm volume. The typical approach for implanting an embolic coil in an aneurysm involves attaching the coil to the distal end of a pushwire, and

introducing the pushwire and coil through a catheter lumen until the coil is pushed into the aneurysm.

The typical manner of detaching the coil from the pushwire involves using a direct current to cause electrolysis of a sacrificial joint between the pushwire and the coil. The coil can then serve to

mechanically occlude a significant volume of the aneurysm and thereby reduce blood circulation

5 within the aneurysm. After a period of time ranging from several hours to several weeks, the volume of the aneurysm can become fully occluded as blood clots about the coil. Eventually, the aneurysm will be reduced and reabsorbed by the body's natural wound healing process. This type of vaso-occlusion system was disclosed by Gugliemli in U.S. Pat. Nos. 5,122,136 and 5,354,295.

Another manner of treating an aneurysm was disclosed by Gugliemli (*see* U.S. Pat. No.

10 5,976,131; 5,851,206) and is described as electrothrombosis. In this particular approach, a catheter and pushwire are used to push a wire coil into the aneurysm that is connected to an electrical source.

The system then delivers radiofrequency (Rf) current to the coil which is adapted to heat the blood volume within the aneurysm to cause thermal formation of thrombus (*see* Pat. No. 5,851,206; Col. 5,

line 5). The conductive coil disclosed by Guglielmi in Pat. No. 5,976,131 has an insulated tip or other

15 arrangements of insulation around the coil to prevent localized "hot spots" (*see* Pat. No. 5,976,131; Col. 3, line 53).

It is believed that several risk factors are involved in any uncontrolled use of significant levels of Rf energy to cause so-called electrothrombosis. Most important, the use of electrical energy to

cause current flow between a coil (first electrode) within an aneurysm and a ground (a second body

20 electrode) will likely cause high energy densities and highly localized heating of tissue that comes into

contact with the coil. If the wall of the aneurysm contacts the energized portion of a coil, there is a significant danger of perforation or ablation of the aneurysm wall that could be life-threatening.

Further, the use of uncontrolled energy delivery to an implanted coil could heat adjacent brain tissue to excessive levels resulting in loss of brain function or even death. For these reasons, the coils disclosed

by Guglielmi were provided with an insulating material covering the tip of the coil that is most likely to come into contact the wall of the aneurysm. However, it is still likely that unwanted localized heating will occur within the aneurysm sac when attempting to cause ohmic heating of the blood volume in an aneurysm by creating Rf current flow between an electrode coil and a body electrode.

5           Another disadvantage of using the typical commercially available wire coil is that the physician must estimate dimensions and volume of the aneurysm and then feed multiple coils into the aneurysm. The deployment of each coil is time consuming, and the detachment of the coil from the introducer pushwire also is time consuming.

#### **SUMMARY OF THE INVENTION**

10           In general, this invention comprises a vascular occlusion system for treating aneurysms that provides a novel class of polymer composite embolic elements that carry thin conductive coatings or conductive conductive fillers to provide the composite with a specified resistivity to electrical current flow. The embolic element is introduced into a targeted site in a patient's vasculature by a microcatheter sleeve. The thin metallic coating allows the embolic element to be soft and flexible, and  
15   more importantly, allows the physician to select any desired length (and volume) of embolic element in vivo for causing mechanical occlusion of the aneurysm. The system of the invention also provides an electrical source and computer controller for feedback modulation of power delivery with a first (low) range and a second (high) range to accomplish two different methods of the invention. The electrical source is coupled to an electrode arrangement at the distal terminus of the catheter sleeve  
20   that contacts the surface of the embolic element as it is slidably deployed from the catheter. Thus, energy is delivered to resistive embolic element directly from the distal terminus of the catheter sleeve. The catheter working end also carries a thermocouple, coupled to feedback circuitry, for sensing the temperature of the deployed embolic element and controlling its temperature via power modulation.

In a method of using an exemplary system, the physician pushes the embolic element from the distal terminus of a catheter into a targeted site in a patient's vasculature to thereby mechanically occlude the aneurysm or other vascular malformation. After disposing a selected length of the embolic element within the targeted site, the physician can optionally actuate the electrical source to deliver low power electrical current from the electrode(s) at the catheter's distal terminus. The electrical energy delivery to the embolic element causes slight resistive heating of the element's surface to formation of layer of coagulum about the deployed embolic element. By this means, the system can controllably create a selected thickness of coagulum about the surface of the embolic element. Thus, the initial deployment of the selected length of the embolic element mechanically occludes or occupies a selected (first) volume of a vascular malformation. Thereafter, controlled energy delivery thermally induces a layer of coagulative to form, thereby providing another selected volume of material to occlude the vascular malformation.

In the next manner of practicing a method of the invention, the physician directs the controller and electrical source to deliver current at a second (higher) power level to the embolic element from the same electrode arrangement at the catheter's distal end. This second power level causes the polymeric element to act like a fuse and divide at the catheter sleeve's terminus. This selected power level, within a fraction of a second, can thermally melt or divide the deployed portion of the continuous polymer embolic element from the remainder of the element still within the catheter sleeve. This aspect of the method of the invention allows the physician to select any length of embolic element intra-operatively under fluoroscopy, which is not possible in the prior art.

In another embodiment of the invention, the polymer composite is adapted for embolic filaments as well other thermally-related medical therapies, wherein the composite comprise a base polymer component with a dispersed thermally non-conductive filler component. In preferred

embodiments, the insulative filler comprises glass or ceramic nanospheres or microspheres. The filler component has a thermal conductivity of less than 5 W/m-K, and preferably less than 2 W/m-K.

In an vaso-occlusive application, the conductively-doped polymer composite with insulative glass microspheres therein can act like a fuse and the insulative properties can further prevent transfer  
5 of thermal effects to adjacent body media.

In another embodiment, the conductively-doped polymer composite with an insulative filler can be used in sacrificial shells of a sphere or tubule that carries a releasable agent. For embolic filaments and sacrificial microspheres, the improvement is that the polymeric composition can have much higher sensitivity to applied electrical energy to sacrifice much more quickly while at the same  
10 time preventing any thermal spread away from the targeted polymer

In other embodiments, the polymer composite with insulative glass microspheres therein can perform as a insulator gel to apply to tissue to protect against thermal damage from an unrelated treatment.

In a vaso-occlusive application, the invention advantageously provides a system and method  
15 for intra-operatively disposing any selected length and selected volume of an embolic element in a targeted site in a patient's vasculature to mechanically occlude a malformation.

The invention provides an embolic member with a specified resistivity by fabricating the a polymer member with at least one very thin conductive surface layer.

The invention provides an embolic member with a specified resistivity by fabricating the  
20 polymer extrusion with conductive microfilaments embedded therein.

The invention provides an embolic member with a specified resistivity by extruding a polymer matrix with conductive particles embedded therein.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Other objects and advantages of the present invention will be understood by reference to the following detailed description of the invention when considered in combination with the accompanying Figures, in which like reference numerals are used to identify like components throughout this disclosure.

FIG. 1 shows a plan view of Type "A" vaso-occlusive system with an elongate catheter sleeve that carries the polymer embolic element made in accordance with the principles of the present invention.

FIG. 2 is an enlarged cut-away view of the working end of the catheter sleeve of FIG. 1 showing an exemplary polymer embolic element with a metallic coating and an electrode arrangement carried within the catheter sleeve.

FIG. 3 is a cut-away view of the working end of FIG. 2 with an exemplary extension member adapted for pushing the polymer embolic element member distally from the catheter sleeve.

FIG. 4 shows the manner in which the working end of FIG. 2 can be introduced over a guidewire.

FIG. 5A is view of view of a portion of an alternative embolic element made up of multiple metallic coated filaments.

FIG. 5B is a view of the passageway in an alternative embodiment of catheter sleeve that cooperates with embolic element of FIG. 5A.

FIG. 5C is a perspective view of an alternative embodiment of extension member adapted to grip the embolic element.

FIG. 6A is a view of the working end of the Type "A" system of FIGS. 1 & 2 disposed in a blood vessel proximate to an aneurysm.

FIG. 6B is a view of the working end of FIG. 6A after a selected length of a distal portion of the polymeric member is disposed in the aneurysm and formed into a tangled mass to occupy a volume of the aneurysm.

FIG. 6C is a graphic view of portion of a polymer embolic element with coagulum formed around the element by resistive heating of the metallic surface to increase the volume of occlusive material within a malformation.

FIG. 7 is a graphic view of a manner of practicing a method of the invention in utilizing a selected level of electrical energy to divide the implanted embolic element from a proximal portion of the polymeric element still within the catheter sleeve.

FIG. 8 is a cut-away view of the working end of Type "B" vaso-occlusive system showing a polymer embolic element with first and second spaced apart metallic coatings made in accordance with the principles of the invention.

FIG. 9 is a sectional view of an embolic element of a Type "C" vaso-occlusive system wherein the embolic element comprises a matrix of a polymer with conductive microfilaments embedded therein.

FIG. 10 is a sectional view of an alternative embolic element of a Type "C" vaso-occlusive system wherein the embolic element comprises a matrix of a polymer with conductive particles distributed therein.

FIG. 11 is a schematic view of an alternative Type "D" vaso-occlusive system and a first step in its method of use wherein a catheter working end introduces a binary media of microspheres with sacrificial shells into an aneurysm sac.

FIG. 12 is a schematic view of another step in utilizing the vaso-occlusive system of FIG. 11 to practice the method of the invention.

FIG. 13 is a view of a final step in practicing a method of the invention with the system of FIGS. 11-12.

FIG. 14 is a schematic view of a polymer composite corresponding to the invention with a glass microsphere filler that exhibits an extraordinarily low thermal conductivity property.

5        FIG. 15A illustrates a polymer composite embolic filament that carries glass microspheres with low thermal conductivity properties.

FIG. 15B illustrates the polymer composite filament of FIG. 15A in use with a catheter that applies energy between bi-polar electrodes to cause a fuse-like effect to divide the filament.

10        FIG. 15C illustrates a polymer composite filament as in FIGS. 15A-15B in a method of use wherein an alternative mono-polar electrode causes a fuse-like effect to divide the filament.

FIG. 16 is a schematic view of the polymer composite with an insulative filler formed into the sacrificial walls of a microsphere.

FIG. 17 is a schematic view of a polymer composite with an insulative filler used in a vaso-occlusive application.

15        FIG. 18A is a schematic view of a tissue volume with a tumor targeted for thermal treatment and an adjacent nerve bundle.

FIG. 18A is a schematic view of the tissue volume of FIG. 18A wherein a polymer composite with an insulative filler is used to protect the nerve bundle.

20        FIG. 19 is a schematic view of a polymer composite that carries glass microspheres with extraordinarily low thermal conductivity properties, wherein the microspheres have a metallic cladding.

FIG. 20 is a schematic view of an alternative vaso-occlusive system that provides a thermoset polymer gel within the catheter that is extrudable from the catheter working end.



FIG. 21 is a sectional view of the vaso-occlusive system of FIG. 20 illustrating the gel-like polymer being altered from a first flowable state to a second non-flowable filament state.

FIG. 22A illustrates a first step in the method of use of the vaso-occlusive system of FIGS. 20-21.

5 FIG. 22B illustrates another step in the method of using the vaso-occlusive system of FIG. 22A.

FIG. 23 shows a plan view of an exemplary hand-held instrument with a working end that extrudes bi-polar conforming gel ribbons.

FIG. 24 is an enlarged cut-away view of the working end of the instrument of FIG. 23  
10 showing spaced apart channels for extruding paired conductive gel ribbons together with an intermediate non-conductive gel ribbon.

FIG. 25 is a graphic illustration of the manner of practicing a method of the invention in extruding a bi-polar gel electrode over a targeted site.

FIG. 26 illustrates an alternative embodiment of instrument and its method of use in extruding  
15 a bi-polar gel electrode over a targeted site.

## **DETAILED DESCRIPTION OF THE INVENTION**

1. Type "A" embodiment of vascular occlusive system. FIG. 1 shows an elevational view of a Type "A" catheter system **5** for occluding an aneurysm or other vascular malformation. The catheter system has a proximal handle or manifold **8** as is known in the art that is coupled to an elongate microcatheter sleeve **10**. FIG. 2 is a cut-away view of the working end **11** of catheter sleeve **10** that  
20 illustrates the metallic-coated elongate thread or filament element **12** corresponding to present invention that can be passed axially through the cooperating microcatheter sleeve **10**. The flexible embolic element **12** defines a proximal portion **20a** still carried within catheter sleeve **10** and a distal

thread portion **20b** that is pushed outward of the catheter. In this exemplary embodiment, the embolic element **12** has an oval or flattened cross-section, but other cross-sectional shapes are suitable.

In this exemplary embodiment, an internal bore or passageway **22** within the catheter sleeve **10** is adapted to carry the embolic thread element **12** as well as to receive a slidable extension member **24** for pushing the polymer thread element **12** from the distal termination **26** of the catheter (*see* FIG. 3). As can be seen in FIGS. 2 & 3, the cross-sectional form of passageway **22** in the catheter sleeve has a first oval-shape bore portion indicated at **28a** for carrying the polymer thread element **12** and a second round-shape bore portion indicated at **28b** for slidably receiving the round extension member **24**. The second bore portion **28b** also is adapted for sliding over a guidewire **29** as shown in FIG. 4.

It should be appreciated that the embolic element **12** and cooperating passageway **22** in the catheter sleeve **10** can be formed in several cross-sectional shapes and configurations (*e.g.*, round, flattened and flexible, braided, etc.) and is shown in FIGS. 5A-5B with the embolic element comprising a flattened braid of polymer microfilaments. The cooperating extension member **24** may have and suitable type of mechanism for pushing, pulling, helically advancing, or otherwise expelling the embolic element **12** from distal termination **26** of the catheter sleeve.

Referring now to FIGS. 1 & 2, it is possible to describe several features and characteristics of embolic thread element **12** that adapt it for use in occluding an aneurysm sac or any other vascular malformation. The embolic element **12** has a core **30** of a continuous length of a flexible biocompatible polymeric material, such as nylon, PET, polyamide, aramid fiber, urethane or Kevlar<sup>®</sup>.

The total length of the embolic element or member **12** may range from about 40 cm. to 2000 cm. The cross-sectional dimension of embolic element **12** may range from about 0.0005" to .030" in a round cross-section element, or similar cross-sectional area in any rectangular or other sectional shape. A suitable polymer material can be fabricated in an extrusion process, for example, by Polymicro Technologies LLC, 18019 N. 25th Ave., Phoenix, Arizona 85023-1200. The polymer embolic

element **12** further carries a radio-opaque composition as is known in the art (*e.g.*, BaSO<sub>4</sub>, BiO<sub>3</sub>) to allow fluoroscopic viewing of embolic element **12** as it is maneuvered within a patient's vasculature.

The core **30** of the embolic element **12** preferably (but optionally) is somewhat porous thus resulting in an irregular surface indicated at **33** to improve the gripping surface of thin-layer conductive or metallic

5 coating **40** on the embolic element as is described next. FIGS. 5A-5B show an embolic element **12** comprising a plurality of small diameter filaments **42** woven into a flexible braid, with each filament having a metallic coating as described below. A braided embolic element **12** such as depicted in FIG. 5A also would provide a suitable surface **33** for gripping with extension member **24** as described below. It should be appreciated that the flexible embolic element may have a curved or coiled repose  
10 shape, and then be straightened as it is passed through the catheter sleeve. Upon deployment, the embolic element would again assume its repose coiled shape to facilitate its introduction into an aneurysm.

As can be seen in FIG. 2, the embolic element **12** carries a thin-layer conductive or metallic coating **40** that has a selected electrical resistivity for accomplishing a method of the invention

15 described below. The metallic coating **40** may be any suitable biocompatible material that can be formed in, or deposited on, the elongate polymeric element **12**, such as gold, platinum, silver, palladium, tin, titanium, tantalum, copper or combinations or alloys of such metals, or varied layers of such materials. A preferred manner of depositing a metallic coating **40** on the polymer element comprises an electroless plating process known in the art, such as provided by Micro Plating, Inc.,  
20 8110 Hawthorne Dr., Erie, PA 16509-4654. The preferred thickness of the metallic coating ranges between about .00001" to .005". More preferably, the coating thickness ranges between about .0001" to .001". Still more preferably, the thickness of the conductive coating ranges between about .0005" to .0007". As will be described below in the Type "C" embodiment, the polymer element also may be

extruded with conductive filaments or particles embedded within the polymer matrix of core 30 of the element.

Of particular interest, the combination of the core 30 and metallic or conductive coating 40 of the embolic element 12 provides a selected resistivity to current flow that ranges from about 1 ohm to 500 ohms per 10 cm. length of the embolic element 12 to cause controllable heating about the surface 33 of embolic element 12. More preferably, the element provides a resistivity ranging between about 5 ohms to 250 ohms per 10 cm. length. Still more preferably, the core 30 and conductive coating 40 provide a selected resistivity ranging between about 30 ohms to 60 ohms per 10 cm. length of the embolic element 12.

FIGS. 2 & 3 further illustrate that the distal end of catheter sleeve 10 carries a conductive electrode surface indicated at 44 about a distal region of bore portion 28a that carries embolic element 12. The electrode 44 is coupled to electrical lead 46 that extends within the wall 48 of the catheter to its proximal handle end and to electrical source 50 and controller 55. It should be appreciated that the electrical lead 46 can be a part of a helical braid reinforcement within the catheter sleeve. As can be easily understood by viewings FIGS. 2 & 3, the elongate embolic element 12 can be pushed distally from bore portion 28a, and no matter the axial position of the embolic element, and electrode 44 will substantially contact the metallic surface 40 of the polymer element 12. As will be described below in the method of the invention, the electrical source 50 and electrode arrangement of catheter 10 in combination with the metallic coating of the polymer element 12 are adapted to (i) facilitate rapid occlusion of an aneurysm, and (ii) to sever or divide the polymer thread element 12 to thereby implant any selected length of distal portion 20b of polymer element 12 within in the aneurysm while retaining a proximal length 20a of the polymer element in bore 28a of the catheter. As shown in FIG. 3, the electrode 44 is shown for convenience at the distal end of the catheter sleeve. Preferably, the electrode 44 is spaced slightly inward or proximal from the distal termination 26 of the sleeve to prevent any

substantial electrode surface from being exposed to the blood volume proximate to a targeted treatment site.

In the system shown in FIGS. 2 & 3, the exemplary polymer element **12** is very soft and flexible, for example, having the flexibility characteristics of a common thread or suture. In order to  
5 deploy the polymer thread element **12** from distal termination **26** of catheter sleeve **10**, this embodiment utilizes a slidable extension member **24** that has unidirectional gripping elements **57** (herein alternatively called barbs) about a distal region **58** of the extension member **24**. As can be understood in viewing FIG. 2, an axial movement or projection of extension member **24** from sleeve **10** will cause the barb elements **57** to grip the embolic element and pull it from bore portion **28a**.  
10 When the extension member **24** is moved proximally in bore portion **28b**, the barb elements will slide over surface **33** of embolic element **12** thus leaving a selected length of the embolic element disposed outside distal termination **26** of the catheter sleeve. The barb or gripping elements **57** may be provided in extension member **24** may comprise cuts into the surface of a polymer extension member **24**. Alternatively, the gripping elements may comprise a fiber or other type of hair-like filament **59**  
15 bonded to the surface of an extension member **24** as shown in FIG. 5C.

The catheter sleeve **10** while carrying the polymer embolic element in bore portion **28a** may be introduced into vasculature over a guidewire **29** as shown in FIG. 4. The guidewire then can be removed and be replaced by the extension member **24**. To facilitate the slidable introduction of the extension member **24** and grip elements into bore portion **28b** while embolic element **12** is carried  
20 within bore portion **28a**, the extension member may cooperate with a very thin-wall sleeve **62** of Teflon<sup>®</sup> or any other suitable material to prevent the gripping elements **57** from gripping the embolic element **12** as the guidewire is replaced with the extension member **24**. As can easily understood from viewing FIG. 3, to expose the distal portion **58** of the extension member **24** and gripping elements **57**,

the thin-wall sleeve **62** can be retracted from the gripping elements by pulling it proximally at the handle **8** of the catheter.

The system **5** further provides feedback control mechanisms within controller **55** for modulating energy delivery to electrode **44** and thereby to the conductive component of the embolic element. Referring again to FIG. 3, at least one thermocouple **88** is provided at either surface of electrode **44** to measure the temperature of the electrode which is substantially the same as the surface temperature of the embolic element in contact therewith. The thermocouple **88** is linked to controller **55** by an electrical lead (not shown). The controller **55** is provided with software and algorithms that are adapted to modulate power delivery from electrical source **50** to maintain the temperature of the embolic element (or electrode **44**) at a particular level or within a particular temperature range, in response to feedback from the sensor.

Now turning to FIGS. 6A-6B, the manner of using the catheter system **5** to introduce the polymer embolic element **12** into a cerebral aneurysm indicated at **100** or any other targeted vascular site is shown. In FIG. 6A, it can be seen that working end **11** of catheter sleeve **10** is introduced through blood **101** flowing in vessel **102** until its distal termination **26** is positioned adjacent to, or partially within, the aneurysm **100**. Typically, the catheter is guided to the aneurysm over guidewire **29** that is accommodated by bore portion **28b** of the catheter sleeve (*see* FIGS. 4 & 6A). In FIG. 6B, it can be seen that guidewire **29** has been withdrawn from catheter passageway **28b**, and thereafter the extension member **24** has been introduced back through the same passageway. The (optional) thin-wall sleeve **62** as shown in FIG. 3 is withdrawn to expose gripping elements **57** at distal portion **58** of the extension member. FIG. 6B depicts an elongate distal portion **20b** of the embolic element **12** being disposed in the aneurysm sac **100** which has been caused by pushing the extension member **24** to and fro thereby causing the grip elements **57** to engage surface **33** of embolic element **12** and successively carry small axial lengths of element **12** distally into the aneurysm under fluoroscopic

control. In this manner, any selected length of distal portion **20b** of polymer element **12**, for example from about 5 cm. to 200 cm. for a typical aneurysm, can be fed into the malformation. The selected length and volume of embolic element **12** thereby displaces blood **101** and occupies a selected (first) volume of the vascular malformation.

5           As can be seen in FIG. 6B, the volume of aneurysm **100** can be substantially occupied with the embolic element **12**, depending on its flexibility, to accomplish a first aspect of the method of the invention. In effect, the embolic element **12** causes an initial partial mechanical occlusion of the aneurysm volume by implanting a selected volume of occlusive material (*i.e.*, the entangled length of polymer element **12**) within the aneurysm which displaces a similar volume of blood **101** and thereby  
10 slows blood flow through the aneurysm and pressure therein. Next, a second novel aspect of the method of the invention is practiced wherein electrical energy is controllably delivered to embolic element **12** to increase the volume of occlusive material within the aneurysm by adding a layer of coagulum **104** about the polymer embolic element **12** thereby occupying a second volume of the aneurysm.

15           More in particular, referring to FIGS. 6B & 6C, after the selected length of distal portion **20b** of polymer element **12** is fed into aneurysm **100** under fluoroscopic control, the physician actuates the electrical source **50** via controller **55** to deliver electrical energy to electrode **44**. The contact between electrode **44** and metallic surface **40** of polymer element **12** causes current flow along the metallic surface **40** of the entangled element and within the patient's body to a return electrode such as a  
20 ground pad in contact with the patient's body. The selected resistivity designed into the combination of metallic coating **40** and embolic element core **30**, as described above, causes resistive heating of the element **12**. The temperature of the surface **33** of the embolic element (as well as slight active ohmic heating of blood about the element **12**) causes denatured blood products and coagulum to adhere about surface **33** of the embolic element. As depicted graphically in FIG. 6C, the thermally-induced

coagulation of blood **101** causes a substantial layer of coagulum **104** to form around the embolic element **12** to thus provide a greater volume of occlusive material within the aneurysm **100**. In a preferred mode of operation, the thermocouple **33** (see FIG. 3) together with feedback circuitry to the controller **55** are used to modulate power delivery to electrode **44** to maintain the embolic element at the catheter terminus at a pre-selected temperature level for a selected period of time. The method of invention maintains the surface temperature of embolic element **12** within a range of about 45° C. to 100° C. More preferably, the surface temperature of the embolic element is maintained within a range of about 65° C. to 90° C. to create the desired coagulum. This aspect of the method of the invention thus increases the volume of occlusive material within the vascular malformation to further mechanically reduce blood circulation within the defect. Thereafter, the occlusive material (embolic element and coagulative layer) within the aneurysm then rapidly will cause accumulation of platelets and other clotting factors about the occlusive material to complete the occlusion of the aneurysm volume as a result of the body's wound healing response to the occlusive material volume within the aneurysm **100**.

In accomplishing the above-described method of the invention, the electrical energy delivery provided by source **50** and controller **55** can be in the radiofrequency range and at a first power level ranging between about 1 watt and 50 watts. More preferably, the power level ranges between about 5 watts and 15 watts. It is proposed that current flow for about 5 seconds to 1200 seconds will cause the desired thickness of coagulative material to form around the embolic element **12** to assist in the mechanical occlusion of an aneurysm or other vascular defect. It should be appreciated that the duration of power delivery is a factor in creating a desired thickness of coagulative material on the embolic element. However, the process of causing the formation of a coagulative layer about the embolic element is essentially self-terminating, which adds to the safety of practicing the method of the invention. The method is self-terminating in the sense that as the coagulative layer builds to the



desired selected thickness, the layer serves as an insulative layer and thereby prevents further denaturation of blood compositions (or ohmic heating of blood proximate to the embolic element.

The method of using an embolic element having a resistivity in the selected range described above has the advantage of preventing any possibility of creating energy densities (“hot spots”) within the aneurysm wall that could perforate the aneurysm sac. The low power levels utilized in this method of the invention can easily cause resistive heating of the metallic surface coating **40** for coagulation purposes, but cannot cause significant localized current flows (*i.e.*, energy densities) that could perforate a vessel wall, or create energy densities that could cause ohmic heating of collateral brain structure. Of particular importance, the thermally-induced coagulative process is effectively self-terminating since the temperature level at surface **33** of the metallic coating **40** will become insulated by the coagulum, thus preventing overheating of the interior or the aneurysm.

FIG. 7 graphically illustrates the next step of the method of the invention that involves separation of the distal portion **20b** of embolic element **12** entangled within aneurysm **102** (*see* FIG. 6B) from proximal portion **20a** of embolic element **12** still within the catheter sleeve **10**. In order to accomplish the separation of the embolic element **12** according to the invention, the physician actuates electrical source **50** via controller **55** to deliver current flow to electrode **44** that has a selected second (higher) power than the previously described power levels. As can be understood in FIG. 7, the insulative coagulum around the embolic element **12** will substantially prevent current flow at the second higher power level to course through the endovascular media, thus eliminating the possibility of high localized current densities. However, at the interface **107** between electrode **44** and metallic surface in contact with the electrode, the current flow will create a transient high energy density in and about metallic coating **40** and core **30** of element **12** to cause thermal melting of the polymer core to thereby divide the embolic element **12**. To divide the embolic element, it is believed that a power level ranging between about 5 watts and 100 watts is suitable. More preferably, the power level is

within the range of about 10 watts to 30 watts. It is believed that current flow for about 0.01 seconds to 20 seconds will divide the embolic element. Following the division of the implanted embolic element **12**, the catheter **10** that carries the proximal portion **20a** of the embolic element is withdrawn from the patient's vasculature.

5           The previously described means of dividing the embolic element with electrical energy has the particular advantage of allowing the physician to implant any desired length of the embolic element **12** within an aneurysm or other vascular defect. The physician simply can advance a length the polymer element into the defect under fluoroscopy until the entangled volume appears optimal, and then deliver electrical energy at the first and second power levels to (i) add coagulative volume to the occlusive  
10   material in the vascular defect, and then (ii) to separate the implanted embolic element **12** from the remainder of the element still within the catheter. This method of the invention, of course, can be practiced for implanting an embolic element without utilizing electrical energy to add a coagulative layer to the embolic element as described above.

          In another embodiment of embolic element **12**, the polymer or the metallic coating is formed  
15   in a coiled or curved shape and the material has a memory of such a curved shape. The flexible embolic element **12** then conforms to a generally linear configuration for feeding through a catheter sleeve. Upon deployment beyond the distal terminus of the catheter sleeve, the embolic element then will substantially assume its curved or coiled shape which will assist in its insertion into an aneurysm.

          2. Type "B" embodiment of vaso-occlusive system. FIG. 8 shows a cut-away view of a Type  
20   "B" catheter system **205** for occluding an aneurysm, other vascular defect or malformation or any targeted site within a patient's vasculature. The catheter system is similar to the previously described embodiment and has a proximal handle or manifold **8** coupled to an elongate microcatheter sleeve **210** that terminates in working end **211**. As can be seen in FIG. 8, this system comprises a metallic-coated elongate member **212** that can be passed axially through cooperating bore **222** in the microcatheter

sleeve **210**. This Type “B” system differs from the previously disclosed system in that the flexible continuous embolic member **212** (that defines proximal portion **220a** and distal thread portion **220b**) functions in two alternative manners: (i) the flattened embolic member **212** is substantially stiffened to allow it to be pushed outward from a handle end **8** of the catheter sleeve without requiring a pushing member or extension member as described above, and (ii) the polymer embolic member **212** carries first and second spaced apart metallic coating portions to act as resistive elements and to further act as a bi-polar delivery system to perform alternative methods of the invention in creating coagulative material and in dividing the polymer embolic member **212** after implantation in a vascular malformation.

In this exemplary Type “B” system embodiment, the internal bore **222** is shaped to receive the flattened embolic thread member **212** in a rectangular shaped bore portion indicated at **228a**. Additionally, the catheter sleeve is adapted to slide over a round guidewire (not shown) that is accommodated by the round shape bore portion **228b**. In this embodiment, the embolic thread member **212** again has a body core **230** of a continuous length of a flexible polymeric filament. The polymer embolic member **212** again carries a radio-opaque composition.

As can be seen in FIG. 8, this alternative embodiment of embolic member **212** carries first and second opposing thin-wall metallic coating portions **240a** and **240b** that extend the length of the embolic member **212**. The metallic coating in this embodiment again has a selected resistivity to current flow that ranges from about 1 ohm to 500 ohms per 10 cm. length, although a lesser resistivity also is functional for some methods of the invention. For example, the opposing metallic coating portions **240a** and **240b** can act as bi-polar electrodes as will be described below. In such an application, the first and second metallic portions **240a** and **240b** extends along first and second sides **241a** and **241b** of the entire length of the embolic member **212**. It can be seen that these first and second metallic surfaces define a center-to-center dimension and can act as bi-polar electrodes, since

the surface portions are spaced apart on either side of a medial non-metallic surface portion indicated at **243**.

FIG. 8 further illustrates that working end **211** of catheter sleeve **210** carries spaced apart first and second conductive electrodes **244A** and **244B** on either side of bore portion **228a** that carries embolic member **212**. The electrodes **244A** and **244B** are coupled to electrical leads **246a** and **246b** in wall **248** that extend to electrical source **50** and controller **55**. As can be understood by viewing FIG. 8, the elongate polymer member **212** is substantially stiff so that it can be pushed distally from bore portion **228a** from the handle end of the catheter, and the electrodes **244A** and **244B** will always be in contact with the respective metallic surface portions **240a** and **240b** of the polymer element **212**.

Alternatively, the embolic member can be pushed distally by an extension member as described previously.

The manner of using catheter system **205** to perform the methods of occluding a cerebral aneurysm **100** can be easily described, still referring to FIG. 8. The elongate polymer member **212** is passed through the catheter sleeve **210** and thereby fed into the aneurysm **100** similar to the graphic representation of FIG. 6B. Thereafter, a guidewire (if used) is withdrawn from the catheter passageway **228b**. Thus, the aneurysm sac can be substantially occupied with embolic member **212** to partially mechanically occlude the aneurysm volume.

Next, the physician actuates electrical source **50** via controller **55** to deliver electrical energy to common polarity electrodes **244A** and **244B**. The contact between electrodes **244A** and **244B** and the metallic surface portions **240a** and **240b** of embolic member **212** causes current flow along the metallic surfaces of the entangled member in cooperation with a return electrode such as a ground pad. The selected resistivity of the metallic surface portions **240a** and **240b** of polymer element **212** then will coagulate blood about the surface of the embolic member **212**, generally as described previously to add to the volume of implanted occlusive material.

In a more preferred method of operation, the electrical source **50** and system **205** is provided with circuitry that allows controller **55** to programmably deliver bi-polar Rf current at a first power level to electrodes **244A** and **244B** which are in contact with the opposing metallic surface portions **240a** and **240b** of polymer member **212** to cause current flow *between* the metallic surface portions **240a** and **240b**. This manner of bi-polar current flow is advantageous since it will not cause high current densities in any endovascular media that might then threaten perforation of the aneurysm wall. Such bi-polar flow thus will rapidly cause a coagulative layer on the embolic member (generally between the metallic surface portions **240a** and **240b**) to thereby add to the volume of occlusive material within the aneurysm. In using the paired metallic surface portions **240a** and **240b** in such a bi-polar energy delivery modality, the metallic coatings may provide any lesser resistivity to current flow for performing the method of the invention.

In another energy delivery modality, the controller may sequence delivery of mono-polar Rf current to the working end **211** in cooperation with a ground pad and bi-polar flow between the paired metallic surface portions **240a** and **240b** to cause coagulum to form about the embolic member **212**.

The system further may use a thermocouple (not shown) and feedback circuitry as described above to maintain the surface of the embolic member within the desired temperature range as described above.

The use of the paired metallic surface portions **240a** and **240b** in a bi-polar mode is particularly adapted for use in the next step of the method of the invention that involves separation of the distal portion **220b** of embolic member **212** entangled within aneurysm **102** (*cf.* FIG. 6B) from proximal portion **220a** still within catheter sleeve **210**. In using this embodiment, the physician actuates electrical source **50** via controller **55** to deliver bi-polar Rf current flow between electrodes **244A** and **244B** at a selected second (higher) power level than used in the coagulation modality. In this case, the second power level causes the core **230** of embolic member **212** to resemble a fuse as the current courses between the electrodes to thus divide embolic member **212** at the distal termination

226 of the catheter sleeve. It is believed that the method of using bi-polar Rf current flow between paired electrodes will allow separation of the embolic member 212 within a range of about 0.1 to 10 seconds. Again, this embodiment of the invention then allows any suitable length of embolic member 212 to be introduced into the aneurysm—and then separated at the catheter end.

5 In another Type “B” embodiment, the emboli member may have a transverse section in the shape of a “C” (not shown) to partially wrap around a guidewire or a pusher member (*see* FIG. 3). It can be easily understood that such a cross-sectional shape would allow the “C” shape to function in the fashion of rapid-exchange catheter systems as are known in the art to insert over a guidewire. Further, this embodiment would allow bi-polar electrode surfaces on opposing and spaced apart inner  
10 and outer surfaces of the embolic member to otherwise function as described above.

3. Type “C” vaso-occlusive system. This alternative Type “C” system uses a catheter sleeve as described in the Type “A” embodiment above. This system differs only in the construction of elongate embolic member 312 shown in FIGS. 9 and 10. The flexible continuously extruded embolic member 312 again comprises a substantially polymer core together with a conductive component that  
15 provides the member with a specified resistivity. In one alternative embodiment of Type “C” embolic member shown in FIG. 9, the member 312 comprises a polymer matrix 345 that is co-extruded with micro-filaments 350 of any suitable conductive material embedded therein, such as tungsten, stainless steel or carbon fiber. The micro-filaments 350 can be partially exposed at the surface of the member to contact the electrode arrangement carried at the distal termination of the catheter sleeve. In another  
20 alternative Type “C” embolic member shown in FIG. 10, the member 312 comprises a polymer matrix 345 with embedded particles 360 of any suitable conductive material to thereby provide the resistivity specified above. The polymer conductive-resistive matrix of embolic member 312 functions as a fuse to divide the embolic member at the distal end of a catheter as described in the Type “A” embodiment.

4. Type “D” vaso-occlusive system. FIG. 11 provides a schematic illustration of an exemplary Type “D” vaso-occlusive system **500** that is adapted to fill an aneurysm sac with novel media **510** corresponding to the invention that can be altered from a first flowable state to a second more solidified state. The system and media **510** are directly related to the conductive-resistive polymer matrix described in the Type “C” embodiment above.

In FIG. 11, the system of the invention is shown schematically wherein a binary system of biocompatible agents are encapsulated in microspheres **512** (collectively). The microspheres have an exterior sacrificial shell portion indicated at **515** that is of a conductive matrix material as described previously. The interior or cores **522** of the hollow microspheres **512** comprise either a first or second composition (indicated at “A” or “B” in FIG. 15) that when mixed together cause a polymerization process between the compositions that will alter the media **510** from a flowable media to a substantially non-flowable media, e.g., a solid or stiff gel-like material. Thus, the media **510** in its flowable state—with first and second types of microspheres therein—can be introduced into an aneurysm from an opening in the distal termination of a catheter, or from a port **530** in the side of the catheter’s working end. Any type of pusher mechanism can be used to expel the flowable media **510** from the catheter. Preferably, the flowable media **510** carries radio-opaque materials or any other material that can cooperate with an imaging system to allow the physician the ability to view the introduction of the media into an aneurysm **525** (FIG. 11).

The sacrificial shell portions **515** of the microspheres can be of a degradable material similar to materials described previously that have conductive particles distributed therein. In one embodiment, the polymer shell material **515** carries particles that can generally be described as “radiosensitive” in that they respond to electromagnetic energy of a selected frequency. Thus, the catheter corresponding to the invention can carry energy deliver means for reducing, degrading, melting, disintegrating or otherwise fracturing the sacrificial shell portions **515** of the microspheres.

In one embodiment, the sacrificial shell can be a wax or lipid with radiosensitive particles therein that can be elevated in temperature (i) by resistive heating due to current flow from an electrode **535** on the catheter working end or (ii) by inductive heating from an emitter electrode as is known in the art.

Thus, the invention provides a vaso-occlusive system that comprises a flowable media **510** that carries a volume of microspheres **512** of first and second types, wherein each type of microsphere has a sacrificial shell **515** that surrounds an interior core portion **522**. The core portions, when allowed to interact, form a binary system for polymerizing the media **510** into a non-flowable gel or a solid.

Now turning to FIG. 11, the distal working end **540** of a catheter is shown schematically as being introduced to the region opposing the neck **524** of an aneurysm **525**. A pusher **542** is used to expel a volume of media **510** from the port **530** which is directed into the aneurysm. The axial movement and angular rotation of the catheter is assisted by suitable markings on the catheter that cooperate with an imaging system. During navigation of the catheter, the port **530** can be maintained in a closed state by a slidable cover, or by a burstable film or the like. The volume of media **510** in FIG. 11 is illustrated for convenience with “A” and “B” particles (indicated at **512a** and **512b**) that are grossly out of scale. In practice, the microspheres can have a dimension across a principal axis thereof ranging between about 10 nanometers and 100 microns. More preferably, the microspheres have a dimension across a principal axis ranging between about 100 nanometers and 100 microns. FIG. 11 further shows that the catheter working end **540** carries an optional balloon system **556** for engaging the walls **558** of the blood vessel to insure that all of the media **510** is directed into the aneurysm sac.

Referring next to FIG. 12, the distal working end **540** is illustrate delivering energy to the volume of media **510** contained in the aneurysm sac **525**. The delivering of energy is indicated by energy field **EF** that in this embodiment consists of electrical current between first polarity electrode **535** and a return electrode **565** that can be a ground pad as is known in the art. This step of the method



causes resistive heating of the sacrificial shell portions **515** of the microspheres in a very brief time interval until the shells degrade to release their contents.

FIG. 13 next schematically illustrates the interaction of the released cores **522** wherein the “A” and “B” compositions create a non-flowable volume of media **510** that occludes the aneurysm sac.

5 FIG. 13 further illustrates the steps of collapsing the balloon member **556** and withdrawing the catheter from the targeted site.

In another embodiment (not shown), the catheter working end **540** can carry opposing polarity spaced apart first and second electrodes for delivering current to the conductive sacrificial shell portions **515** of the media in a bi-polar electrode arrangement in the working end.

10 In another embodiment (not shown), the energy emitter can be the terminal end of an optic fiber coupled to a light source, such as a laser. The sacrificial shell portions **515** of the media can carry any suitable chromophore for cooperating with a selected wavelength of the light source to again thermally degrade the sacrificial shell portions **515** of the microspheres. In all other respects, the system for occluding a vascular malformation is the same as described above.

15 5. Biomedical polymer composites. In another aspect, the invention comprises a new class of micro- or nanostructured polymer composites **600** that can be used for fuse-like embolic filaments as in FIG. 10. The new polymer composite **600** also can be used in several other biomedical applications, including forming the walls of hollow shells, spheres and the like. The invention comprises a polymer composite **600** of a micro- or nanostructured insulative filler material **610**  
20 dispersed within a base polymer **615** to form a matrix. In one embodiment of fuse-like or sacrificial polymer composite **600**, the base polymer carries a conductive particle filler **618** dispersed within the matrix to provide a specified electrical resistivity as described in the earlier embodiments above. In general, the biomedical polymer composite has specified electrical resistance properties that allows it to perform in a fuse-like manner to melt, degrade or sacrifice in response to selected electrical

parameters, such as voltage, current and duration of electrical energy delivery. For example, the sacrificial polymer composite can be used as a “fuse” to divide an embolic filament at the end of a catheter as in FIG. 7, or can be used to form the sacrificial walls of hollow spheres as in FIGS. 11-13. At the same time, the polymer composite **600** has unique thermal insulative properties and can be used to prevent propagation of thermal effects within the polymer or adjacent body structure.

The micro- or nanostructured insulative filler **610**, in a preferred embodiment depicted in FIG. 14, comprises hollow microspheres that have extraordinarily low thermal conductivity properties. In one example, the filler material **610** consists of micron-dimension or nanoscale microspheres that are fabricated of a glass. In one embodiment, the insulative filler material comprises Q-CEL<sup>®</sup> hollow microspheres manufactured by Potters Industries, Inc., 820 Lufkin Road Apex, NC 27502-0298. The desired low thermal conductivity properties are provided by a glass material in the form of soda-lime glass or borosilicate. In another embodiment, the filler **610** can be hollow microspheres of Pyrex or any ceramic with a suitable low thermal conductivity. Thermal conductivity is a measure of the ability of a material of body to conduct heat, determined by the rate of heat flow normally through an area in the material divided by the area and by minus the component of the temperature gradient in the direction of flow, measured in W/m-K (watts per meter per degree Kelvin). In one embodiment, the filler material defines a thermal conductivity of less than about 5 W/m-K. Preferably, the insulative filler material **610** defines a thermal conductivity of less than about 2 W/m-K. More preferably, the insulative filler material **610** defines a thermal conductivity of less than about 0.5 W/m-K.

Referring to schematic view of FIG. 14, the base polymer **615** can be any biocompatible crystalline or semi-crystalline polymer. For example, the base polymer **615** can be at least one of the following materials: a polyamide, a polycarbonate, a polystyrene, a polyacrylonitrile, a polyacetal, a thermoplastic modified cellulose, a polysulfone, a thermoplastic polyester such as PET, poly(ethyl acrylate), or poly(methyl methacrylate), a nylon, a fluoropolymer such as polyvinylidene fluoride, an ethylene tetrafluoroethylene, or blends of two or more of the above polymers. The polymers described

above are well known and are available from Dow Chemical, Union Carbide or Dupont-Mitsui Polychemicals Co., Ltd., all of which manufacture one or more of the above polymers. For embolic filaments and sacrificial hollow bodies, the insulative polymer composite **600** can provide much higher sensitivity to applied electrical energy to thereby melt or sacrifice instantly, while at the same time preventing thermal spread away from the targeted region of the polymer composite. The conductive filler material **618** can be any suitable biocompatible material, for example at least one of copper, aluminum, gold, iron, magnesium, molybdenum, nickel, palladium, platinum, silver, tantalum, tin, titanium, tungsten, zinc, or zirconium.

Referring to FIG. 15A, the advantages of the sacrificial polymer composite **600** can be understood in the context of a sacrificial embolic filament **630** for filing aneurysms, similar to that illustrated in FIG. 7 above. In the embodiment of FIG. 15A, the filament **630** entirely comprises the polymer composite **600** as described above with insulative filler microspheres **610** dispersed therein (not-to-scale). The filler material **610** preferably makes up more than about 5% by volume of the final polymeric composite **600**. The filler material can comprise as much as about 80% by volume of the final polymeric composite **600**. The polymer of the filament also is doped with electrically conductive particles **618** or microfilaments, such as carbon to provide the specified resistivity. The filament **630** has a stiffness akin to a monofilament fishing line that is suitable for pushing through channel **632** in catheter **634** from the handle end of the catheter. As can be seen in FIG. 15B, the catheter working end has opposing bi-polar electrodes **635a** and **635b** that are coupled to an electrical source **636** for applying energy to thermally melt and divide the filament **630**. In use, the insulative microsphere filler **610** allows the filament to melt more rapidly since the melt volume is less due to the percentage volume of the microsphere filler **610**. More important, the insulative microsphere filler **610** prevents the transfer of heat about the filament and into blood or adjacent body structure. Thus, the fuse-like process of dividing the filament **630** requires only instantaneous application of energy which will cause no collateral thermal effects damage.

In FIG. 15C, a polymer composite filament **630** is shown in use with a catheter working end **634** that utilizes a mono-polar ring electrode **638** to melt and divide the filament. The ring electrode **638** extends 360° about the end of the catheter and cooperates with a return ground pad **639** as is known in the art. As depicted in FIG. 15C, the filament **630** can be divided and melted across a very narrow cross-section of the filament wherein Rf energy density is localized at the end of the catheter. The heat effect caused within the filament **630** is prevented from propagating axially along the filament because of the insulative filler **610** within the polymer. In a filament **630** without an insulative filler **610**, the filament would melt and divide across a broader cross-sectional region indicated at **D** in FIG. 15C. Thus, the insulative filler **610** has the effect of confining Rf energy density to a surface of the polymer or a plane proximate to the active electrode.

In another embodiment, the insulative filler material **610** consists of hollow micro- or nanospheres or tubes that also carry a selected gas within the hollow body. An inert gas (e.g., argon) would be useful in preventing or limiting oxidation in the composition during mixing and thereafter. The hollow micro- or nanospheres also can have a partial vacuum therein and can be compounded with the base polymer in a partial vacuum which can enhance the thermally non-conductive properties of the final polymer composite.

In another embodiment shown schematically in FIG. 16, a polymer composite **600** similar to that described above is used to fabricate the walls **640** of any suitably dimensioned hollow sphere or tubule **642**. The polymer wall **640** again carries an insulative filler material **610** having a thermal conductivity of less than about 5 W/m-K. Preferably, the insulative filler material **610** has a thermal conductivity of less than about 2 W/m-K, and more preferably less than about 0.5 W/m-K. In this embodiment, the filler material **610** also can be in the form of particles rather than hollow spheres, since the walls of a hollow shell may be very thin. The polymer again carries conductive filler particles **618** to provide a specified resistivity. The cores **644** of such hollow bodies carry the binary media as in FIGS. 11-13 that when released from the shells **642** can intermix and thereby change from

a first flowable state to a second more solidified state. The improvement relates to the instantly thermally sacrificial properties of the polymer composite, which is similar to the sacrificial melting of the filament of FIG. 7. FIG. 17 is a schematic illustration of the use of such sacrificial walls **640** of microspheres wherein thermal propagation would be limited, which could in turn cause only the polymerization of a cap portion **646** of the implanted material.

In another embodiment, the sacrificial walls **640** are provided with hollow microspheres that also carry any drug. The sacrificial walls **640** can be melted or sacrificed by any thermal means, such as electric current delivered to conductively doped polymer composite walls having a specified resistivity, or inductive heating of ferromagnetic doped polymer composites, or light energy heating of a chromophore doped polymer composite.

In another aspect of the invention, illustrated schematically in FIGS. 18A-18B, the insulative polymer composite or gel **650** can be used not to resistively heat and sacrifice the composite structure, but rather to thermally protect a targeted site against thermal effects while performing a thermally-mediated therapy on adjacent tissue. Such a thermally protective polymer composite **650** would be particularly useful, for example, in spine surgeries or neurosurgery applications wherein nerves must be protected from thermal damage. In the cartoon of FIG. 18A, a body structure **652** is shown that has a nerve bundle **654** in close proximity to a tumor **656** that is targeted for thermal ablation by laser or Rf energy delivery. FIG. 18B next illustrates the physician utilizing an introducer device **670** to introduce the polymer gel to cover the nerve bundle **654**. The polymer composite or gel **650** can be any biocompatible or bio-absorbable base polymer **615** that preferably carries ultra-low thermally conductive nano- or microsphere filler **610** as described above. The filler material **610** can make up more from about 5% to 95% by volume of the final polymeric composite or gel **650**. In this embodiment, the polymeric composite or gel **650** obviously does not carry a conductive filler component. As can be seen in FIG. 18B, an instrument such as a laser or Rf device **675** is indicated in

phantom view in position to thermally ablate the tumor with nerve bundle 654 thermally protected by gel 650.

The polymer composites above are fabricated by mixing a precursor of the matrix material, i.e., the base polymer 615, with the non-conductive filler 610 and then processing the compositions to form the desired matrix material. The filler material or materials are mixed into the melt-state base polymer 615 until the filler materials are well dispersed. By any technique known in the art, the mixing is accomplished in a system that provides a temperature higher than the melting point of the polymeric base 615. In mixing the polymer base 615 with the insulative microspheres 610, together with the optional additives described below, the objective of mixing is to create a uniform dispersal of the filler material. In one method of fabricating the polymer composite 600 or 650, it has been found that an important step is providing an inert gas atmosphere (e.g., argon gas) in which the polymer is mixed at a selected temperature ranging between about 125° C. and 300° C. The protective gas atmosphere substantially eliminates oxidation that otherwise would occur to some extent within the base polymer. A particular advantage is that the mixing or compounding step can be extended in duration—even to one or more hours of mixing—without oxidation and degradation of the composite to allow uniform dispersal of the filler.

Other fillers can be included in the polymer composite 600 or 650, such as particles of magnesium or titanium, which are reductive and can assist in preventing oxidation within the polymer chains of the base polymer 615. The thermoplastic polymer base 615 can carry other additives known in the art, such as anti-arcing compositions, anti-oxidizing agents (magnesium oxide or titanium oxide), anti-ozonizing agents, cross-linking agents or any combination thereof. In the fabrication process, the mixture can also be treated with various cross-linking processes, both chemical and radiation (e.g., gamma, UV, E-beam irradiation), to cross-link the polymer or co-polymers of the matrix. In another embodiment, the hollow microspheres can carry any low thermal conductivity gas in the hollow core. For example, the microsphere cores can carry an anti-oxidant gas (e.g., H<sub>2</sub>) or a

gas that serves as a foaming agent. Alternatively, the hollow cores can be a partial vacuum. All these variations can add to the utility of the invention.

In another embodiment (not shown), the polymer composite or gel **650** as in FIG. 18A can carry a reversible thermochromic material that changes in color in response to thermal effects. A thermochromic agent or polymer can be incorporated into the base polymer during mixing. Articles containing 0.1% to about 2.0% by weight of thermochromic pigments in the host polymer can be designed to have a visually observable, reversible thermochromic transitions. Thermochromic materials are available from Chemsong, Inc., 923 Hawthorne Lane, West Chicago, IL 60185. It can be easily understood that the thermochromic effect, as in FIG. 18B, would allow the physician to easily guard against tissue overheating by simple observation of the thermochromic gel.

In another embodiment, the polymer can carry light-reflecting filler particles for reflecting light energy of selected wavelengths. Thus, the nerve bundle of FIG. 18B can be protected when light energy is used to thermally treat adjacent tissue.

In another embodiment depicted in FIG. 19, the polymer composition **680** has a base polymer **615** with an insulative component **610'** of a different type. The insulative filler **610'** again can be nano- or microspheres that have the same thermal conductivity properties as described above. In this embodiment, the insulative filler materials have a thin metal coating or cladding **685**, for example a nanometric layer of gold, silver, platinum or another suitable metallic material that can be deposited by electroless plating or other means. In one embodiment, the metal coating is of a ferromagnetic material that will thus respond to inductive heating from an electromagnetic source. In this polymer composite, the single filler material functions as both the insulative component and the electrically conductive component to provide the specified resistivity. In another embodiment, the polymer composite can be used in any medical device, catheter or the like wherein the metallic coating provides radiopacity. In another embodiment, the base polymer **615** carries insulative hollow particles

as described above for use in medical instruments to provide a polymer that responds optimally to ultrasound imaging.

FIGS. 20 through 22B illustrate an alternative embodiment of the invention wherein the polymer composite similar to that described above is used as a vaso-occlusive system **690**. The system includes a catheter **692** with working end **695** that can introduce any selected length of a polymer composite **700** into an aneurysm. The polymer composite **700** this time comprises a flowable media within a catheter channel rather than being a solid filament. The polymer composite **700** again consists of a substantial volume of an insulative filler **710** in a base polymer **715** together with a conductive filler component **718**, as described previously. More in particular, referring to FIG. 20, an elongate catheter **692** as is known in the art has a working end **695** with a central channel **722** extending along the catheter's axis **725**. The catheter diameter and the thickness of the wall **726** that surrounds the central channel **722** can be any suitable dimension to provide suitable flexibility and pushability for navigating to a targeted endovascular location.

The sectional view of FIG. 21 shows that the channel **722** of catheter working end **695** carries first and second spaced apart electrodes **730A** and **730B** that have opposing polarities as defined by the electrical source **735** coupled to the electrodes. In the exemplary embodiment of FIGS. 20 and 21, the electrodes **730A** and **730B** are shown as being positioned on opposing sides of the channel **722** but the electrodes also can be ring-type electrodes spaced apart axially close to the open termination **736** of the channel. Preferably, the exposed surfaces of the electrodes **730A** and **730B** are spaced inward from the open channel termination **736**.

Still referring to FIG. 20, an elongate portion of channel **722** carries a fluid or gel-like composite **700** wherein the base polymer **715** comprise a biocompatible thermoset type of polymer. The composite **700** carries any suitable conductive or "radiosensitive" compositions **718**, which provide the thermoset base polymer **715** with the specified resistivity that cooperates with the



electrodes **730A** and **730B** to elevate the temperature of the composite **700** when “engaged” by the electrode arrangement. In one embodiment, the radiosensitive filler composition **718** comprises electrically conductive carbon particles ranging from about 10 nm to 100 microns in cross section. The conductive filler alternatively can be any other conductive particle or microfilament of gold, silver or the like. Also, the composite **700** carries a radio-opaque composition (not shown) that cooperates with a selected imaging system to allow imaging of the introduction of the composite into an aneurysm.

FIGS. 20 and 21 illustrate that the gel-like composite **700** can extend through a very elongate section of channel **722** to carry a sufficient volume of media to fill a targeted aneurysm. The flowable composite **700** can be pushed outward of the distal termination of channel **722** by a pusher rod mechanism indicated at **748**. The distal end of the pusher **748** is in contact with the gel-like composite **700** and the proximal end of the pusher extends outwardly of the handle portion (not shown) of the catheter for manipulation and advancement by the physician. In FIG. 21, it can be seen that contemporaneous pushing of composite **700** through the region of its engagement by energized electrodes **730A** and **730B** will cause its elevation in temperature and conversion to thermoset solid polymer **700'**. This solid filament-like media **700'** can be extended or extruded in any selected length in the aneurysm (FIG. 22A).

It should be appreciated that the media **700'** can be extended outwardly from the distal tip of the catheter or from a side port in the side wall of the catheter working end. Further, the working end can carry one of more balloons or other expansion structures for stabilizing the catheter working end proximate to the neck of an aneurysm. Still further, the catheter working end can carry a plurality of opening through which the media **700'** can be pushed with each such opening having a cooperating electrode arrangement.

Now turning to FIGS. 22A-22B, the method of practicing the invention utilizing the system of FIG. 20 is illustrated. In FIG. 22A, the working end of catheter 692 is shown as being introduced endovascularly to the neck of an aneurysm. In FIG. 22B, the physician then activates the energy source while contemporaneously advancing the pusher 748 to extend, extrude and alter the media into a thermoset filament media 700' that extends from the open catheter end into the aneurysm. In this first step of the method of the invention in one mode of operation, a computer controller coupled to the electrical source can be coupled to a pressure sensor or flow sensor in the working end of the catheter 692 to modulate energy delivery between selected power levels depending on the rate of flow of media across the interface with the electrodes. In another mode of operation, the catheter working end can carry multiple pairs of electrodes and deliver a different selected level of power to each electrode pair. By this means, stresses can be induced into the thermoset filament 710' resulting in the filament assuming a curved shape after exiting the catheter. The multiple paired electrodes also can be carried at various different depths within the channel 722 to induce stresses in the extruded filament media 700' to produce a curvilinear, twisted or helical filament shape, of any combination thereof. It is believed that such a curvilinear filament will be more easily packed into an aneurysm.

As can be seen in FIG. 22B, at least one selected length of a solid filament media 700' has been introduced into aneurysm to substantially occlude the malformation. Another optional step and mode of operation of the invention can be understood from FIG. 22B, which is similar to that described in the Types "A" and "C" embodiments and FIG. 6C above. This method relates to a controlled method of energy delivery to the extended filament media 700' within the aneurysm in a self-limiting process to cause coagulative material to form around the filament to further occlude the aneurysm. This aspect of the method comprises the steps of (a) providing the filament conductive polymer composite that defines a positive temperature coefficient (PTC) of resistance; (b) engaging body media such as blood with the polymer composite; (c) applying electrical energy via electrodes to the polymer composite;

and (d) self-limiting the application of Rf energy to the body media as a result of the PTC effect in the polymer composite. In other words, at any time that a selected portion of the filament is elevated over a switching temperature of the PTC as it senses and responds to adjacent ohmically heated body media, that portion of the filament becomes substantially resistive and terminates current flow therethrough. To accomplish this method of the invention, the controller would typically define both electrodes **730A** and **730B** of the catheter with a first polarity that would cooperate with a return electrode comprising a ground pad (not shown). In this aspect of the method, another selected power level would be provided to accomplish the energy delivery to the blood.

FIG. 22B further illustrates the final step of the method of the invention, as in FIG. 7B, wherein the system detaches the extruded filament media **700'** from the catheter and the gel composite **700** that is still carried within the catheter lumen **722**. In one method, the gel composite **700** is sufficiently soft so that the extruded portion naturally decouples from the gel at the interface between the non-thermoset portion **700** and the thermoset portion **700'**. In another embodiment, as when the gel composite **700** is stiff or the media carries conductive microfilaments, the detachment can be accomplished as described previously with a very brief application of higher level of energy to melt the filament wherein it functions as a fuse.

FIGS. 23-25 are views of an alternative instrument **780** for delivering energy to tissue surfaces that uses polymer composites **800** similar to that described above. Again, the polymer composite **800** consists of a substantial volume of an insulative filler **810** in a base polymer **815** together with a conductive filler component **818**. In one embodiment of FIG. 23, the instrument has a proximal handle **820** as is known the art with an elongate introducer portion **822** that extends to a working end **824**. The introducer portion **822** can have any suitable cross-section and length for use in endoscopic or open surgeries. The handle **820** carries a pivotable actuating lever or slide actuator **826** for extruding the flowable composite **800** from the working end **824**. The handle also carries a trigger

indicated at **828** for actuating electrosurgical energy delivery to the working end and thereby to the polymer gel composite **700**. The gel-extruding actuator **826** and electrosurgical trigger **828** optionally can be interlinked to work in unison.

FIG. 24 is a partially cut-away view of the working end **824** of instrument **780** for extruding and painting the flowable composite **800** across a targeted site on a body structure, wherein the composite can function as a bi-polar electrode arrangement. The working end **824** defines paired spaced apart (first and second) channels **832A** and **832B** that carry the flowable conductive polymer composite **800** that can have the consistency of a thick paint or gel. It can be seen that each channel **832A** and **832B** terminates in a media outflow port or opening indicated at **835A** and **835B**, respectively. First and second electrodes **840A** and **840B** have exposed surfaces that extend inwardly from the media outflow ports **835A** and **835B**. Each electrode **840A** and **840B** is coupled by an electrical lead to an electrosurgical generator **845** and **846** (see FIG. 23).

The working end **824** further defines an intermediate channel **850** that extends to a third media outflow port **855A** that extrudes a flowable non-conductive polymer composition **860**. The intermediate outflow port **855A** is positioned between the paired outflow ports **835A** and **835B** that extrude the flowable conductive media **800**. In one preferred embodiment, the conductive media **800** and the non-conductive media **860** are adapted with different colors (and/or transparency) to provide a visual indicator of the non-conductive media being properly extruded between the conductive gel ribbons. For example, the conductive gel ribbons can be a first color or be transparent or translucent, and the intermediate non-conductive gel can be a second contrasting color. Both the electrically conductive gel **800** and non-conductive gel preferably carry the insulative microsphere filler material **810** as described above, which will assist in preventing unwanted thermal effects in tissue that is not targeted for treatment.

In one exemplary embodiment shown in FIG. 24, the instrument provides means for simultaneously extruding ribbons of gel from the working end **824**. In FIG. 24, the instrument has a set of cooperating axially-extending plungers indicated at **862**. In this embodiment, the reservoir of conductive gel composite **800** and non-conductive gel composite **860** consist of the selected lengths of the gel in channels **832A**, **832B** and **850** within introducer member **822**. The instrument carries mechanical linkage as is known in the art wherein the lever actuator **826** would ratchet to advance the set of plungers **862** distally to push the gel ribbons outwardly from the distal end.

In another embodiment (not shown) the channels **832A**, **832B** and **850** within the working end are in fluid communication with first and second gel reservoirs **865** and **866** (FIG. 24) that carry the conductive media **800** and non-conductive media **860**, respectively. Such gel reservoirs (see FIG. 24) can be carried in the handle **820** of the instrument or be remote from the handle and communicate therewith through flexible tubing. In this embodiment, a back-and-forth stroke of the lever actuator **826** would pull volumes of gel media into channels **832A**, **832B** and **850**, and then extrude the gel volumes from the working end. Any other pressurization systems or hydraulic system can be used to extrude that gels and fall within the scope of the invention.

Referring again to FIG. 24, it can be seen that the working end **824** is covered with a thin film seal indicated at **888** that can be removed just prior to use. Optionally, the seal **888** can be a burstable film element that bursts on the application of pressure when the gel begins to be extruded from the working end. It should be appreciated that the introducer member **822** (see FIG. 23) can be flexible, articulating, deflectable or deformable and fall within the scope of the invention. For example, a flexible or articulating gel bi-polar electrode extruding system can be developed for introduction through a working channel of an endoscope.

Now turning to FIG. 25, the method of the invention is illustrated wherein energy is applied to a treatment site **TS** in the form of controlled depth ohmic heating based on the center-to-center

distance between the conductive gel ribbons. In FIG. 25, it can be seen that the two ribbons of conductive media **800** and **800'** are extruded from the working end **824** at the same time as an intermediate ribbon of non-conductive media **860** is extruded. The gel extrusion process allows the physician to "paint" the working end **824** across a targeted treatment site **TS**. Contemporaneous with the extrusion of the gel ribbons, the physician actuates the trigger **828** to apply alternating Rf current to the opposing polarity electrodes **840A** and **840B**. The conductive gel ribbons **800** and **800'** are in contact with the electrodes **840A** and **840B** at the same time that the gel conforms to, and flows over, the irregular surface of the anatomic structure. No matter how irregular the tissue surface, the Rf energy applied to the electrode ribbons will create a substantially uniform depth of ohmic heating of tissue, whether the objective is coagulation at lower temperatures, or a form of tissue ablation at higher temperatures. In FIG. 25, the arrows indicate the current flow within the tissue surface.

The type of energy delivery illustrated in FIG. 25 can be used in sealing the surface of an organ, such as a liver, kidney, pancreas or lung. In a similar method of use, an instrument can be dimensioned to apply bi-polar gel electrodes around the pulmonary vessels to create elongate lesions in the vessel walls for creating, or blocking, conduction pathways as is known in the art.

The system optionally provides feedback control mechanisms within controller **846** for modulating energy delivery to electrodes **840A** and **840B** and thereby to the conductive gel electrodes. Referring again to FIG. 25, at least one thermocouple **890** can be provided proximate to the electrodes to measure the temperature of each electrode which resembles the surface temperature of the targeted site. The thermocouple **890** is linked to controller **846** by an electrical lead (not shown). The controller **846** is provided with software and algorithms that are adapted to modulate power delivery from electrical source **845** to maintain the temperature of the electrodes at a particular level or within a particular temperature range, in response to feedback from the sensor.

In a preferred mode of operation, the thermocouple **890** (see FIG. 24) together with feedback circuitry to the controller **846** are used to modulate power delivery to the electrodes to maintain their temperature at a pre-selected temperature level for a selected period of time. The method of invention maintains the electrodes within a range of about 60° C. to 200° C. More preferably, the surface temperature of is maintained within a range of about 70° C. to 100° C.

In another preferred embodiment, the conductive gel ribbons **800** and **800'** can carry a biocompatible or bioresorbable thermochromic composition. Such a thermochromic material can be designed to change its color in response to temperature and thereby can provide the physician with an excellent visual indicator of the temperature of the gel, which reflects the temperature of the treated tissue. The phenomenon of thermochromism can be defined as the reversible change of a color of a material in response to change in temperature. As one example, the composition can exhibit a thermodynamic phase between the pure solid and pure liquid phases and be microencapsulated and carried in a polymer host that is dispersed in the gel. At any temperature below a selected "event" temperature, the thermochromic material can be designed to be a transparent or translucent solid. At a selected thermochromic transition temperature or event temperature, the material will reflect visible light of a unique wavelength to provide an indicator to the physician.

The temperature sensitive thermochromic material also can be adapted to reversibly change its color at any selected thermochromic transition temperature, for example a temperature between 50 C° to 200 C°, depending on the application. More preferably, the thermochromic transition temperature is between 70 C° to 100 C°. The thermochromic transition temperature is typically based on the structure of the polymer or oligomer-based pigment that can be adjusted by chemical modifications. The transition color can be any selected color, for example the thermochromic material can change from translucent to red at the selected thermochromic transition temperature. One source of thermochromic materials for including in the gel matrix of the invention is International Ink Co., 775 Dorsey Street, Gainesville GA 30501 (<http://www.iicink.com/temptell.htm>).

Now turning to FIG. 26, an alternative working end 895 and its method of use are illustrated for applying a bi-polar composite gel electrode to a targeted site. In this embodiment, the two ribbons of conductive media 800 and 800' again are extruded from the working end 824. In this embodiment, the channel 850 that extrudes the intermediate ribbon of non-conductive media 860 is configured to extend *between and over* the exterior surfaces of the ribbons of conductive media 800 and 800'. The system and method illustrated in FIG. 26 would thus prevent electrosurgical energy delivery to non-targeted tissues that might fall into contact with the gel-electrode ribbons since the entire surface of the extruded gels is encapsulated with a layer of the non-conductive gel. Further, the gel strips could be painted over one another to provide a more complete coverage of a targeted site.

In any embodiment of conductive media 800, the scope of the invention includes any flowable media such as a gel, paste, liquid, colloid or suspension in which the matrix of the media comprises a biocompatible flowable material together with a biocompatible conductive composition therein. The invention further includes any gel, paste or liquid with a saline solution component that can provide a change in media conductivity as the media is dried by energy delivery therethrough. In one embodiment, the desiccation of a saline component can be designed to make greater contacts between the conductive microfibrils or compositions in the media to thereby increase its conductivity. In another embodiment, a highly conductive saline can be used wherein its desiccation can reduce contact between conductive particles to decrease its conductivity.

In any embodiment of conductive media 800, all materials and components of the media can be bioabsorbable. Further, the media can create a seal over the treatment area. Antibiotics and other pharmacologically active compositions can be provided in the media.

As described above, the hollow ceramic or glass nano- or microspheres when dispersed within a polymer, gel or fluid volumes (collectively imageable media) are well suited to allow ultrasound imaging of the volume after introduction into the interior of a patient's body. The nano- or



microspheres also can be fabricated, at least in part, of a radiosensitive imaging material, or clad in such a radiosensitive material layer. For example, a gold layer can be provided on the nano- or microspheres to allow for x-ray and similar types of imaging. The scope of the system embodiments and methods corresponding to the invention encompasses the use of such imageable media for introduction into vascular malformations in the interior of the body for uses that benefit from ultrasound imageability. The scope of the invention includes the use of such imageable media for any therapeutic applications at any location in a patient's body.

In one example, biocompatible nano- or microspheres can be dispersed in any biocompatible fluid or gel-like media, including collagen filler media, for use as an imageable filler material for dermatology and reconstructive surgery applications. In one example, the inventive media can be used after tumor removal to replace the excised tissue volume. In breast lumpectomies, the filler material then would be imageable to ascertain treatment margins and allow a baseline 3D volume for later reference in follow-up exams. In this system embodiment, the media functions only in an imaging capacity.

In another embodiment, the imageable media can function in a linked manner to function both in an imaging function and in an energy application function. In one example, the inventive imageable filler material can be introduced into a patient's body as a dermatological filler, wherein the filler also carries an energy-responsive composition as described above (a magnetic responsive composition, a radiosensitive composition, or a chromophore) for cooperating with an external energy source. Such a filler can be used advantageously in a thermally mediated treatment to cause collagen shrinkage, to cause a wound-healing response for inducing collagen formation, or generally to cause thermal tissue stimulation. The method and system of the invention comprises (i) using the ultrasound imaging means to scan a selected area or volume of tissue; (ii) utilizing algorithms in an imaging controller system to determine the distribution of the media within the scanned area, or more particularly the distribution of the energy-responsive composition within the scanned area; and (iii) utilizing the data

on media distribution to adjust energy levels and localization of energy delivery to cause a selected thermal effect within the tissue—no matter the lack of control over media migration in the tissue.

Those skilled in the art will appreciate that the exemplary embodiments and descriptions of the invention herein are merely illustrative of the invention as a whole. Specific features of the invention may be shown in some figures and not in others, and this is for convenience only and any feature may be combined with another in accordance with the invention. While the principles of the invention have been made clear in the exemplary embodiments, it will be obvious to those skilled in the art that modifications of the structure, arrangement, proportions, elements, and materials may be utilized in the practice of the invention, and otherwise, which are particularly adapted to specific environments and operative requirements without departing from the principles of the invention. The appended claims are intended to cover and embrace any and all such modifications, with the limits only being the true purview, spirit and scope of the invention.